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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/051,395

05/08/98

MATHISON

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EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1653

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34

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/051,395

Applicant(s)

Mathison et al.

Examiner

ANISH GUPTA

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 28, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9, 11, 13-15, and 38-89 is/are pending in the application.
- 4a) Of the above, claim(s) 9, 11, 13, 39-49, 51, 53, 55, 57, 59, 61, and 64- is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 14, 15, 38, 50, 52, 54, 56, 58, 60, 62, and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 33 20) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 9-14-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/051,395 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

2. Newly submitted claim 13, 39-50 and 64-89 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 13, and 39-49, 64-70 and 79-87 correspond to the Group III of restriction dated 11-9-98. Similarly, claims 72-78 correspond to Group II, claim 88 corresponds to Group IV and claim 89 corresponds to Group V of the same restriction. In the response to the restriction, dated 1-19-99, Applicants elected Group I, drawn to the peptides of the formula R1-X1-X2-R2 and a method for prevention an anaphylactic reaction in mammals. Although Applicants elected with traverse, Applicants did not distinctly and specifically point out the supposed errors in the restriction. Thus Group II-V were withdrawn from consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13, 39-49 and 64-89 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In the response dated 1-19-99, Applicants also elected the species Phe-Glu-Gly. Thus the pending claims have been examined to the extent the read on the elected species. Thus, claim 9, 11, 51, 53, 55, 57, 59, and 61 are withdrawn from consideration as corresponding to non-elected species.

Claims 7-8 38, 50, 52, 54, 56, 58, 60, and 62-63 have been examined as corresponding to the elected Group and elected species.

Claim Rejections - 35 USC § 112
Second Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7-8, 14-15, 38, 50, 52, 54, 56, 58, 60, 62-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims state, for variable R2, that it can be “a sequence of 1 to 3 amino acids.” However, a single amino acid does not constitute a sequence.

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 50, 52, 54, 56, 58, 60, 62-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment or reduction of anaphylactic reactions with the peptide FEG, does not reasonably provide enablement for any peptide corresponding to the formula R1-X1-X2-R2 for the same purpose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When

the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention are drawn to peptides modulate anaphylactic, endotoxin and inflammatory reactions in mammals.

(2) The state of the prior art

The art has not developed with respect to the peptide of the formula R1-X1-X2-R2 and prevention of anaphylactic reactions using such peptides.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

As with all peptides, activity is based on the 3-dimensional structure of the peptide. That is, the peptide has to have the proper structure to recognize the specific receptor for the peptide to be active. It is known in the art that the three dimensional structure of the peptide cannot be based on structure alone. For example, in peptide chemistry Ngo et al. teach that for proteins and peptides, a " 'Direct' approach to structure prediction, that of directly simulating the folding process, is not yet possible because contemporary hardware falls eight to nine orders of magnitude short of the task." (see page 493 in Ngo et al.) Accordingly, it is not known if an efficient algorithm for predicting the structure exist for a protein or peptide from its amino acid alone (see page 492 in Ngo et al.). Thus, activity of a given peptide can not be based on its structure alone. Similarly, the Rudinger article (see the conclusions in particular) states "The significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study."

(5) The breadth of the claims

The broadest claims are open to peptides of the formula R1-X1-X2-R2, where R1 is an amino acid sequence of three amino acids or NH2, X1 is an aromatic amino acid, X2 is any amino acid and R2 is a peptide up to three amino acids which are aliphatic amino acid residues.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples

The specification does provide guidance as the reducing and treating effects on anaphylactic reactions with the peptide FEG. However, the specification fails to adequately provide ample guidance that any peptide corresponding to the formula R1-X1-X2-R2 will be effective in treating, reducing or preventing anaphylactic reactions. The example given in utilize a single peptide corresponding to the sequence FEG. However, the claims are open to much broader sequences that may not even have conservative substitutions corresponding to FEG. It has been established in the art that one can not readily determine the effects of substitutions of amino acids to the native sequence based on structure alone. Again, Ngo et al. teach that for proteins and peptides, a “ ‘Direct’ approach to structure prediction, that of directly simulating the folding process, is not yet possible because contemporary hardware falls eight to nine orders of magnitude short of the task.” (see page 493 in Ngo et al.) Accordingly, it is not known if an efficient algorithm for predicting the structure exist for a protein or peptide from its amino acid alone (see page 492 in Ngo et al.). Thus, activity of a given peptide can not be based on its structure alone. Similarly, the Rudinger article (see the conclusions in particular) states “The significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study.”

Moreover, the Board of Appeals has held *Ex parte Sudilovsky*, where it was held that the disclosure was non-enabling since:

“[t]he specification, though highly detailed, is devoted solely to a description of compounds stated to be known ACE inhibitors. The remainder of the specification is directed to how to make tablets and solutions for injection. Any disclosure regarding utility is confined to broad allegations and suggestions without substantiating working example. As stated in *In re Glass*, 492 F.2d 1228, 181 USPQ 31, 35 (CCPA 1974), ‘the strong feeling one gets from reading the entire specification is that either appellant did not have possession of the details of a single operative process or, if he did, he chose not to divulge them.’”

Ex parte Sudilovsky, 21 U.S.P.Q2d 1702 (BPAI 1991). Similarly, the disclosure of the instant application, with regard to the peptide corresponding to the formula R1-X1-X2-R2 and prevention of anaphylactic reactions, is confined to broad allegations and suggestions without substantiating working examples. Although working examples are not necessary in the specification, lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. When a patent applicant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. *In re Novak*, 306 F.2d 924, 134 USPQ 335 (CCPA 1962) 4; *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971). In this case, the disclosure has not provided evidence of record of a representative set of compound corresponding the formula and still possessing the claimed activity. Thus, given the unpredictability of the art, undue experimentation would be required to practice the claimed invention.

(8) The quantity of experimentation necessary

Since, the art indicates a level of unpredictability in determining activity of a peptide based on structure alone one would be burdened with undue experimentation to practice the claimed invention for the reasons stated above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 7-8 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sloodstra et al.


The claims are drawn to peptide of the formula R1-X1-X2-R2, wherein the peptide corresponds to the species NH₂-Phe-Glu-Gly.

The reference teaches the tripeptide, Phe-Glu-Gly (see page 92). Therefore, the instant claims are anticipated since R1 is NH2, X1 is Phe, X2-Glu, and R2 is Gly.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


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